# Complete Summary

## GUIDELINE TITLE

ACC/AHA/NASPE 2002 guideline update for implantation of cardiac pacemakers and antiarrhythmia devices: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines.

## BIBLIOGRAPHIC SOURCE(S)

ACC/AHA/NASPE 2002 guideline update for implantation of cardiac pacemakers and antiarrhythmia devices. Bethesda (MD): American College of Cardiology Foundation; 2002. 48 p. [447 references]

## COMPLETE SUMMARY CONTENT



## SCOPE

### DISEASE/CONDITION(S)

Cardiac arrhythmias including those associated with:

- acquired atrioventricular (AV) block
- chronic bifascicular or trifascicular block
- acute myocardial infarction
- hypertrophic obstructive cardiomyopathy
- idiopathic dilated cardiomyopathy
- sinus node dysfunction
- hypersensitive carotid sinus
- neurocardiogenic syncope
- congenital heart disease
- long-QT syndrome
- coronary artery disease (CAD)
- resuscitated cardiac arrest due to ventricular fibrillation (VF) or ventricular tachycardia (VT)
- idiopathic ventricular tachycardia (e.g., Brugada syndrome)
- arrhythmogenic right ventricular dysplasia/cardiomyopathy

- syncope with inducible sustained ventricular tachycardia
- heart failure

## GUIDELINE CATEGORY

Evaluation
Treatment

## CLINICAL SPECIALTY

Cardiology
Internal Medicine
Pediatrics
Surgery

## INTENDED USERS

Physicians

## GUIDELINE OBJECTIVE(S)

- To provide guidelines on the indications for permanent pacing and on indications for implantable cardioverter-defibrillator (ICD) therapy: The focus of these guidelines is the appropriate use of devices (pacemakers and implantable cardioverter-defibrillators), not the treatment of cardiac arrhythmias
- To review and revise the guidelines for implantation of pacemakers and antiarrhythmia devices published in 1998

## TARGET POPULATION

Adults, young adults with congenital heart disease, adolescents, and children with cardiac arrhythmias

## INTERVENTIONS AND PRACTICES CONSIDERED

1. Cardiac pacemakers
2. Implantable cardioverter-defibrillators (ICDs)

Note: The committee considered extending the scope of the guideline to include recommendations for follow-up and device replacement but deferred the decision given other published statements and guidelines on the topic. The material presented in the guideline on pacemaker follow-up is a matter of information. No endorsement is implied.

## MAJOR OUTCOMES CONSIDERED

- Subjective and objective symptom improvement
- Short-term outcomes: Quality of life, exercise capacity

- Long-term outcomes: Sudden death or total mortality; or survival; cardiovascular mortality; incidences of atrial fibrillation; thromboembolic events; heart failure

## METHODOLOGY

### METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Searches of Electronic Databases

### DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Pertinent medical literature in the English language was identified through a search of library databases, and a large number of publications were reviewed by committee members during the course of their discussions. Additionally the committee reviewed documents related to the subject matter previously published by the American College of Cardiology (ACC), the American Heart Association (AHA), and the North American Society for Pacing and Electrophysiology (NASPE).

### NUMBER OF SOURCE DOCUMENTS

Not stated

### METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

### RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

The committee reviewed and ranked the evidence as follows:

A. Data were derived from multiple randomized clinical trials involving a large number of individuals.
B. Data were derived from a limited number of trials involving a comparatively small number of patients or from well-designed data analyses of nonrandomized studies or observational data registries.
C. Consensus opinion of experts was the primary source of recommendation.

### METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
Systematic Review

### DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Writing groups were specifically charged to perform a formal literature review, weigh the strength of evidence for or against a particular treatment or procedure, and include estimates of expected health outcomes where data exist.

## METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

## DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Experts in the subject under consideration are selected from the American College of Cardiology and the American Heart Association to examine subject-specific data and write guidelines. The process includes additional representatives from other medical specialty groups when appropriate. Writing groups are specifically charged to perform a formal literature review, weigh the strength of evidence for or against a particular treatment or procedure, and include estimates of expected health outcomes where data exist. Patient-specific modifiers, comorbidities, and issues of patient preference that might influence the choice of particular tests or therapies are considered as well as frequency of follow-up and cost-effectiveness.

## RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Class I: Conditions for which there is evidence for and/or general agreement that the procedure or treatment is useful and effective.

Class II: Conditions for which there is conflicting evidence and/or a divergence of opinion about the usefulness/ efficacy of a procedure or treatment.

Class IIa: The weight of evidence or opinion is in favor of the procedure or treatment.

Class IIb: Usefulness/efficacy is less well established by evidence or opinion.

Class III: Conditions for which there is evidence and/or general agreement that the procedure or treatment is not useful/effective and in some cases may be harmful.

## COST ANALYSIS

Several studies have addressed the cost-effectiveness of implantable cardioverter-defibrillator (ICD) therapy. The cost-effectiveness ratio compares the total cost of ICD therapy with the total cost of an alternative management strategy such as amiodarone or guided serial drug testing. The overall costs of the ICD have been reduced as the result of nonthoracotomy implantation methods and improvements in ICD reliability and longevity that reduce cost of device replacement and modification. Significant reductions in initial costs have been realized, with newer treatment algorithms eliminating prolonged drug testing.

The early studies of ICD cost-effectiveness were based on mathematical models and relied on nonrandomized studies to estimate clinical efficacy and cost. These studies found cost-effectiveness ratios of $17,000, $18,100, and $29,200 per year of life saved. Another model incorporated costs of nonthoracotomy ICDs and efficacy estimates based on randomized trials and found ICD cost-effectiveness

was between $27,300 and $54,000 per life-year gained, corresponding to risk reduction of 40% and 20%, respectively.

Several completed and ongoing randomized clinical trials have measured cost as well as clinical outcomes and thus can directly estimate ICD cost-effectiveness. The Multicenter Automatic Defibrillator Implantation Trial (MADIT) found a 54% reduction in total mortality and a cost-effectiveness ratio of $27,000 per life-year added. The Canadian Implantable Defibrillator Trial (CIDS), by contrast, found a 20% reduction in total mortality and a cost-effectiveness ratio of $139,000 per life-year added. The cost-effectiveness ratio from the Antiarrhythmics Versus Implantable Defibrillators (AVID) trial was $66,677 per life-year added. This range of results is primarily due to different estimates of the effectiveness of the ICD in reducing mortality, because all showed similar increases in the cost of care among ICD recipients. When the results of all clinical trials were used in a model that projected the full gain in life expectancy and lifetime costs, the cost-effectiveness of the ICD was $31,500 per life-year added, comparable to widely accepted non-cardiac therapies such as renal dialysis ($30,000 to $50,000 per year of life saved). The cost-effectiveness of the ICD is more favorable in patients with an ejection fraction below 35%. In principle, the device is most cost-effective in patients at high risk of arrhythmic death and at low risk of other causes of death. Cost-effectiveness of the ICD would be improved by lowering the cost of the device itself and further improving its reliability and longevity.

### METHOD OF GUIDELINE VALIDATION

External Peer Review
Internal Peer Review

### DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

This document was reviewed and approved by the Board of Trustees of the American College of Cardiology (ACC) and the Scientific Advisory and Coordinating Committee of the American Heart Association (AHA). The 1998 version was reviewed by three outside reviewers nominated by ACC, three outside reviewers nominated by AHA, and individuals representing the American College of Physicians (ACP) and the North American Society for Pacing and Electrophysiology (NASPE). The section "Pacing in Children and Adolescents" was reviewed by additional reviewers with special expertise in pediatric electrophysiology. The 2002 update was reviewed by two outside reviewers nominated by the ACC, two outside reviewers nominated by the AHA, and two outside reviewers nominated by the NASPE. Many of the reviewers´ suggestions were incorporated into the final document.

## RECOMMENDATIONS

### MAJOR RECOMMENDATIONS

Levels of recommendation (I-III) and strengths of evidence (A-C) are defined at the end of the Major Recommendation field.

## Recommendations for Permanent Pacing in Acquired Atrioventricular Block in Adults

### Class I

1. Third-degree and advanced second-degree atrioventricular (AV) block at any anatomic level associated with any one of the following conditions:
    a. Bradycardia with symptoms (including heart failure) presumed to be due to AV block. (Level of evidence: C)
    b. Arrhythmias and other medical conditions that require drugs that result in symptomatic bradycardia. (Level of evidence: C)
    c. Documented periods of asystole greater than or equal to 3.0 seconds or any escape rate <40 beats per minute (bpm) in awake, symptom-free patients. (Shaw, Holman, & Gowers, 1980; Kay, Estioko, & Wiener, 1982) (Levels of evidence: B, C)
    d. After catheter ablation of the AV junction. (Levels of evidence: B, C) There are no trials to assess outcome without pacing, and pacing is virtually always planned in this situation unless the operative procedure is AV junction modification. (Gallagher et al., 1982; Langberg et al., 1989)
    e. Postoperative AV block that is not expected to resolve after cardiac surgery. (Level of evidence: C) (Kastor, 1975; Glikson et al., 1997; Kim et al., 2001)
    f. Neuromuscular diseases with AV block, such as myotonic muscular dystrophy, Kearns-Sayre syndrome, Erb's dystrophy (limb-girdle), and peroneal muscular atrophy with or without symptoms, because there may be unpredictable progression of AV conduction disease. (Level of evidence: B) (Perloff et al., 1984; Hiromasa et al., 1987; Stevenson et al., 1990; James & Fisch, 1963; Roberts, Perloff, & Kark, 1979; Charles et al., 1981; James, 1962)
2. Second-degree AV block regardless of type or site of block, with associated symptomatic bradycardia. (Level of evidence: B) (Strasberg et al., 1981)

### Class IIa

1. Asymptomatic third-degree AV block at any anatomic site with average awake ventricular rates of 40 bpm or faster, especially if cardiomegaly or left ventricular (LV) dysfunction is present. (Levels of evidence: B, C) (Recommendations for pacemaker prescriptions for symptomatic bradycardia: report of a working party of the British Pacing and Electrophysiology Group, 1991; Shaw et al., 1985)
2. Asymptomatic type II second-degree AV block with a narrow QRS. When type II second-degree AV block occurs with a wide QRS, pacing becomes a Class I recommendation (see next section regarding "Pacing for Chronic Bifascicular and Trifascicular Block) (Level of evidence: B) (Strasberg et al., 1981; Recommendations for pacemaker prescriptions for symptomatic bradycardia: report of a working party of the British Pacing and Electrophysiology Group, 1991; Shaw et al., 1985; Connelly & Steinhaus, 1996)
3. Asymptomatic type I second-degree AV block at intra- or infra-His levels found at electrophysiological study performed for other indications. (Level of evidence: B) (Barold, 1991; Kim et al., 1993)

4. First- or second-degree AV block with symptoms similar to those of pacemaker syndrome. (Level of evidence: B)

Class IIb

1. Marked first-degree AV block (>0.30 seconds) in patients with LV dysfunction and symptoms of congestive heart failure in whom a shorter AV interval results in hemodynamic improvement, presumably by decreasing left atrial filling pressure. (Level of evidence: C) (Brecker et al., 1992)
2. Neuromuscular diseases such as myotonic muscular dystrophy, Kearns-Sayre syndrome, Erb's dystrophy (limb-girdle), and peroneal muscular atrophy with any degree of AV block (including first-degree AV block) with or without symptoms, because there may be unpredictable progression of AV conduction disease. (Level of evidence: B) (Perloff et al., 1984; Hiromasa et al., 1987; Stevenson et al., 1990; James & Fisch, 1963; Roberts, Perloff, & Kark, 1979; Charles et al., 1981; James, 1962)

Class III

1. Asymptomatic first-degree AV block. (Level of evidence: B) (See also "Pacing for Chronic Bifascicular and Trifascicular Block.") (Mymin et al., 1986)
2. Asymptomatic type I second-degree AV block at the supra-His (AV node) level or not known to be intra- or infra-Hisian. (Level of evidence: B, C) (Strasberg et al., 1981)
3. AV block expected to resolve and/or unlikely to recur (McAlister et al., 1989) (e.g., drug toxicity, Lyme disease, or during hypoxia in sleep apnea syndrome in absence of symptoms). (Level of evidence: B)

Recommendations for Permanent Pacing in Chronic Bifascicular and Trifascicular Block

Class I

1. Intermittent third-degree AV block. (Level of evidence: B) (Freidberg, Donoso, & Stein, 1964; Gadboys, Wisoff, & Litwak, 1964; Johansson, 1966; Hindman et al., 1978; Donmoyer, DeSanctis, & Austen, 1967; Edhag & Swahn, 1976; Penton, Miller, & Levine, 1956)
2. Type II second-degree AV block. (Level of evidence: B) (Dhingra et al., 1974; Donoso, Adler, & Friedberg, 1964; Ranganathan et al., 1972)
3. Alternating bundle-branch block. (Level of evidence: C) (Josephson, 1993)

Class IIa

1. Syncope not demonstrated to be due to AV block when other likely causes have been excluded, specifically ventricular tachycardia (VT). (Level of evidence: B) (Kulbertus & Collignon, 1969; DePasquale & Bruno, 1973; Dhingra et al., 1974; Scheinman et al., 1977; Denes et al., 1977; McAnulty et al., 1978; Peters et al., 1979; Fisch, Zipes, & Fisch, 1980; McAnulty et al., 1982; Scheinman et al., 1982; Morady et al., 1984; Click et al., 1987; Ezri et al., 1983; Twidale et al., 1988; Englund et al., 1995; Probst et al., 1979; Dhingra et al., 1979; Cheng, 1971)

2. Incidental finding at electrophysiological study of markedly prolonged HV interval (greater than or equal to 100 milliseconds) in asymptomatic patients. (Level of evidence: B) (Scheinman et al., 1982)
3. Incidental finding at electrophysiological study of pacing-induced infra-His block that is not physiological. (Level of evidence: B) (Dhingra et al., 1979)

Class IIb

1. Neuromuscular diseases such as myotonic muscular dystrophy, Kearns-Sayre syndrome, Erb's dystrophy (limb-girdle), and peroneal muscular atrophy with any degree of fascicular block, with or without symptoms, because there may be unpredictable progression of AV conduction disease. (Level of evidence: C) (Perloff et al., 1984; Hiromasa et al., 1987; Stevenson et al., 1990; James & Fisch, 1963; Roberts, Perloff, & Kark, 1979; Charles et al., 1981; James, 1962)

Class III

1. Fascicular block without AV block or symptoms. (Level of evidence: B) (Scheinman et al., 1977; McAnulty et al., 1978; McAnulty et al., 1982; Scheinman et al., 1982)
2. Fascicular block with first-degree AV block without symptoms. (Level of evidence: B) (Scheinman et al., 1977; McAnulty et al., 1978; McAnulty et al., 1982; Scheinman et al., 1982)

Recommendations for Permanent Pacing After the Acute Phase of Myocardial Infarction*

Class I

1. Persistent second-degree AV block in the His-Purkinje system with bilateral bundle-branch block or third-degree AV block within or below the His-Purkinje system after acute myocardial infarction (AMI). (Level of evidence: B ) (Ranganathan et al., 1972; Col & Weinberg, 1972; Ritter et al., 1976; Ginks et al., 1977; Domenighetti & Perret, 1980; Lamas et al., 1986)
2. Transient advanced (second- or third-degree) infranodal AV block and associated bundle-branch block. If the site of block is uncertain, an electrophysiological study may be necessary. (Level of evidence: B) (Col & Weinberg, 1972; Ritter et al., 1976)
3. Persistent and symptomatic second- or third-degree AV block. (Level of evidence: C)

*These recommendations generally follow the ACC/AHA Guidelines for the Management of Patients with Acute Myocardial Infarction. See the National Guideline Clearinghouse summary.

Class IIb

1. Persistent second- or third-degree AV block at the AV node level. (Level of evidence: B)

Class III

1. Transient AV block in the absence of intraventricular conduction defects. (Level of evidence: B) (Col & Weinberg, 1972)
2. Transient AV block in the presence of isolated left anterior fascicular block. (Level of evidence: B) (Ginks et al., 1977)
3. Acquired left anterior fascicular block in the absence of AV block. (Level of evidence: B) (Col & Weinberg, 1972)
4. Persistent first-degree AV block in the presence of bundle branch block that is old or age indeterminate. (Level of evidence: B)* (Col & Weinberg, 1972)

Recommendations for Permanent Pacing in Sinus Node Dysfunction

Class I

1. Sinus node dysfunction with documented symptomatic bradycardia, including frequent sinus pauses that produce symptoms. In some patients, bradycardia is iatrogenic and will occur as a consequence of essential long-term drug therapy of a type and dose for which there are no acceptable alternatives. (Level of evidence: C) (Kay, Estioko, & Wiener, 1982; Kusumoto & Goldschlager, 1996; Rasmussen, 1981)
2. Symptomatic chronotropic incompetence. (Level of evidence: C) (Kay, Estioko, & Wiener, 1982; Kusumoto & Goldschlager, 1996; Rasmussen, 1981; Linde-Edelstam et al., 1992; Gammage et al., 1991)

Class IIa

1. Sinus node dysfunction occurring spontaneously or as a result of necessary drug therapy with heart rate less than 40 bpm when a clear association between significant symptoms consistent with bradycardia and the actual presence of bradycardia has not been documented. (Level of evidence: C) (Shaw, Holman, & Gowers, 1980; Kay, Estioko, & Wiener, 1982; Kusumoto & Goldschlager, 1996; Rasmussen, 1981; Dreifus, Michelson, & Kaplinsky, 1983; Rubenstein et al., 1972)
2. Syncope of unexplained origin when major abnormalities of sinus node function are discovered or provoked in electrophysiologic studies. (Level of evidence: C) (Fisher, 1981; Reiffel & Kuehnert, 1994)

Class IIb

1. In minimally symptomatic patients, chronic heart rate less than 40 bpm while awake. (Level of evidence: C) (Shaw, Holman, & Gowers, 1980; Kay, Estioko, & Wiener, 1982; Kusumoto & Goldschlager, 1996; Rasmussen, 1981; Dreifus, Michelson, & Kaplinsky, 1983; Rubenstein et al., 1972)

Class III

1. Sinus node dysfunction in asymptomatic patients, including those in whom substantial sinus bradycardia (heart rate less than 40 bpm) is a consequence of long-term drug treatment.

2. Sinus node dysfunction in patients with symptoms suggestive of bradycardia that are clearly documented as not associated with a slow heart rate.
3. Sinus node dysfunction with symptomatic bradycardia due to nonessential drug therapy.

### Recommendations for Permanent Pacemakers That Automatically Detect and Pace to Terminate Tachycardias

#### Class IIa

1. Symptomatic recurrent supraventricular tachycardia that is reproducibly terminated by pacing in the unlikely event that catheter ablation and/or drugs fail to control the arrhythmia or produce intolerable side effects. (Level of evidence: C) (Peters et al., 1985; Fisher et al., 1987; Den Dulk et al., 1984; Saksena et al., 1986; Barold et al., 1987)

#### Class IIb

1. Recurrent supraventricular tachycardia or atrial flutter that is reproducibly terminated by pacing as an alternative to drug therapy or ablation. (Level of evidence: C) (Peters et al., 1985; Fisher et al., 1987; Den Dulk et al., 1984; Saksena et al., 1986; Barold et al., 1987; Spurrell, Nathan, & Camm, 1984)

#### Class III

1. Tachycardias frequently accelerated or converted to fibrillation by pacing.
2. The presence of accessory pathways with the capacity for rapid anterograde conduction whether or not the pathways participate in the mechanism of the tachycardia.

### Pacing Recommendations to Prevent Tachycardia

#### Class I

1. Sustained pause-dependent ventricular tachycardia (VT), with or without prolonged QT, in which the efficacy of pacing is thoroughly documented. (Level of evidence: C) (Eldar et al., 1987; Eldar et al., 1992)

#### Class IIa

1. High-risk patients with congenital long-QT syndrome. (Level of evidence: C) (Eldar et al., 1987; Eldar et al., 1992)

#### Class IIb

1. AV re-entrant or AV node re-entrant supraventricular tachycardia not responsive to medical or ablative therapy. (Level of evidence: C) (Fisher et al., 1987; den Dulk et al., 1984; Attuel et al., 1988)
2. Prevention of symptomatic, drug-refractory, recurrent atrial fibrillation in patients with coexisting sinus node dysfunction. (Level of evidence: B)

Class III

1. Frequent or complex ventricular ectopic activity without sustained VT in the absence of the long QT syndrome.
2. Torsade de Pointes VT due to reversible causes.

Recommendations for Permanent Pacing in Hypersensitive Carotid Sinus Syndrome and Neurocardiogenic Syncope

Class I

1. Recurrent syncope caused by carotid sinus stimulation; minimal carotid sinus pressure induces ventricular asystole of more than 3 seconds' duration in the absence of any medication that depresses the sinus node or AV conduction. (Level of evidence: C) (Peretz, Gerein, & Miyagishima, 1973; Brignole et al., 1991)

Class IIa

1. Recurrent syncope without clear, provocative events and with a hypersensitive cardioinhibitory response. (Level of evidence: C) (Peretz, Gerein, & Miyagishima, 1973; Brignole et al., 1991)
2. Significantly symptomatic and recurrent neurocardiogenic syncope associated with bradycardia documented spontaneously or at the time of tilt-table testing. (Level of evidence: B) (Sutton et al., 2000; Connolly et al., 1999; Sheldon et al., 1998; Ammirati, Colivicchi, & Santini, 2001)

Class III

1. A hyperactive cardioinhibitory response to carotid sinus stimulation in the absence of symptoms or in the presence of vague symptoms such as dizziness, light-headedness, or both. (Level of evidence: C)
2. Recurrent syncope, light-headedness, or dizziness in the absence of a hyperactive cardioinhibitory response. (Level of evidence: C)
3. Situational vasovagal syncope in which avoidance behavior is effective. (Level of evidence: C)

Recommendations for Permanent Pacing in Children, Adolescents, and Patients With Congenital Heart Disease

Class I

1. Advanced second- or third-degree AV block associated with symptomatic bradycardia, ventricular dysfunction, or low cardiac output. (Level of evidence: C)
2. Sinus node dysfunction with correlation of symptoms during age-inappropriate bradycardia. The definition of bradycardia varies with the patient's age and expected heart rate. (Level of evidence: B) (Ector, Rolies, & De Geest, 1983; Kay, Estioko, & Wiener, 1982; Mackintosh, 1981)

3. Postoperative advanced second- or third-degree AV block that is not expected to resolve or persists at least 7 days after cardiac surgery. (Levels of evidence: B, C) (Mackintosh, 1981; Lillebei et al., 1963)
4. Congenital third-degree AV block with a wide QRS escape rhythm, complex ventricular ectopy, or ventricular dysfunction. (Level of evidence: B) (Michaelsson, Jonzon, & Riesenfeld, 1995; Pinsky et al., 1982; Moak et al., 2001)
5. Congenital third-degree AV block in the infant with a ventricular rate <50 to 55 bpm or with congenital heart disease and a ventricular rate <70 bpm. (Level of evidence: B, C) (Pinsky et al., 1982; Michaelsson & Engle, 1972)
6. Sustained pause-dependent VT, with or without prolonged QT, in which the efficacy of pacing is thoroughly documented. (Level of evidence: B) (Eldar et al., 1987; Eldar et al., 1992; Moss et al., 1991; Viskin et al., 1996)

Class IIa

1. Bradycardia-tachycardia syndrome with the need for long-term antiarrhythmic treatment other than digitalis. (Level of evidence: C) (Gillette et al., 1991; Rhodes et al., 1995)
2. Congenital third-degree AV block beyond the first year of life with an average heart rate less than 50 bpm, abrupt pauses in ventricular rate that are two or three times the basic cycle length, or associated with symptoms due to chronotropic incompetence. (Level of evidence: B) (Dewey, Capeless, & Levy, 1987)
3. Long QT syndrome with 2:1 AV or third-degree AV block. (Level of evidence: B) (Trippel, Parsons, & Gillette, 1995; Solti et al., 1992)
4. Asymptomatic sinus bradycardia in the child with complex congenital heart disease with resting heart rate less than 40 bpm or pauses in ventricular rate more than 3 seconds. (Level of evidence: C)
5. Patients with congenital heart disease and impaired hemodynamics due to sinus bradycardia or loss of AV synchrony. (Level of evidence: C)

Class IIb

1. Transient postoperative third-degree AV block that reverts to sinus rhythm with residual bifascicular block. (Level of evidence: C) (Krongrad, 1978)
2. Congenital third-degree AV block in the asymptomatic infant, child, adolescent, or young adult with an acceptable rate, narrow QRS complex, and normal ventricular function. (Level of evidence: B) (Michaelsson, Jonzon, & Riesenfeld, 1995; Sholler & Walsh, 1989)
3. Asymptomatic sinus bradycardia in the adolescent with congenital heart disease with resting heart rate less than 40 bpm or pauses in ventricular rate more than 3 seconds. (Level of evidence: C)
4. Neuromuscular diseases with any degree of AV block (including first-degree AV block), with or without symptoms, because there may be unpredictable progression of AV conduction disease.

Class III

1. Transient postoperative AV block with return of normal AV conduction. (Level of evidence: B) (Kertesz et al., 1996; Krongrad, 1978)

2. Asymptomatic postoperative bifascicular block with or without first-degree AV block. (Level of evidence: C)
3. Asymptomatic type I second-degree AV block. (Level of evidence: C)
4. Asymptomatic sinus bradycardia in the adolescent with longest RR interval less than 3 seconds and minimum heart rate more than 40 bpm. (Level of evidence: C) (Greenspan et al., 1988)

Pacing Recommendations for Hypertrophic Cardiomyopathy

Class I

1. Class I indications for sinus node dysfunction or AV block as previously described. (Level of evidence: C)

Class IIb

1. Medically refractory, symptomatic hypertrophic cardiomyopathy with significant resting or provoked LV outflow obstruction. (Level of evidence: A) (Fananapazir et al., 1994; Nishimura, Hayes, et al., 1996; Kappenberger et al., 1997; Nishimura, Symanski, et al., 1996; Maron et al., 1999)

Class III

1. Patients who are asymptomatic or medically controlled.
2. Symptomatic patients without evidence of LV outflow obstruction.

Pacing Recommendations for Dilated Cardiomyopathy

Class I

1. Class I indications for sinus node dysfunction or AV block as previously described. (Level of evidence: C)

Class IIa

1. Biventricular pacing in medically refractory, symptomatic New York Heart Association (NYHA) class III or class IV patients with idiopathic dilated or ischemic cardiomyopathy, prolonged QRS interval (greater than or equal to 130 milliseconds), LV end-diastolic diameter greater than or equal to 55 mm, and ejection fraction less than or equal to 35%. (Level of evidence: A) (Cazeau et al., 2001; Abraham et al., 2002)

Class III

1. Asymptomatic dilated cardiomyopathy.
2. Symptomatic dilated cardiomyopathy when patients are rendered asymptomatic by drug therapy.
3. Symptomatic ischemic cardiomyopathy when the ischemia is amenable to intervention.

Pacing Recommendations After Cardiac Transplantation

Class I

1. Symptomatic bradyarrhythmias/chronotropic incompetence not expected to resolve and other Class I indications for permanent pacing. (Level of evidence: C)

Class IIb

1. Symptomatic bradyarrhythmias/chronotropic incompetence that, although transient, may persist for months and require intervention. (Level of evidence: C)

Class III

1. Asymptomatic bradyarrhythmias after cardiac transplantation.

Recommendations for Implantable Cardioverter-Defibrillator (ICD) Therapy

Class I

1. Cardiac arrest due to ventricular fibrillation (VF) or ventricular tachycardia (VT) not due to a transient or reversible cause. (Level of evidence: A) (Mehta et al., 1992; Saksena et al., 1992; Bardy et al., 1992; Mirowski et al., 1980; Lehmann et al., 1988; Tchou et al., 1988; Fogoros, Fiedler, & Elson, 1987; Winkle et al., 1989; Fogoros et al., 1990; Newman et al., 1992; Powell et al., 1993; Crandall et al., 1993; PCD Investigator Group, 1994; Zipes & Roberts, 1995; Wever et al., 1996; The Antiarrhythmics versus Implantable Defibrillators (AVID) Investigators, 1997; Borggrefe et al., 1994; Morady et al., 1993; Wever et al., 1995; Krol & Saksena, 1996; Connelly et al., 2000; Kuck et al., 2000)
2. Spontaneous sustained VT in association with structural heart disease. (Level of evidence: B) (Mehta et al., 1992; Saksena et al., 1992; Bardy et al., 1992; Mirowski et al., 1980; Lehmann et al., 1988; Tchou et al., 1988; Fogoros, Fiedler, & Elson, 1987; Winkle et al., 1989; Fogoros et al., 1990; Newman et al., 1992; Powell et al., 1993; Crandall et al., 1993; Saksena, for the PCD Investigator Group, 1994; Zipes & Roberts, 1995; Wever et al., 1996)
3. Syncope of undetermined origin with clinically relevant, hemodynamically significant sustained VT or VF induced at electrophysiological study when drug therapy is ineffective, not tolerated, or not preferred. (Level of evidence: B) (Wever et al., 1996; Connelly et al., 2000; Saksena et al., 1996; Nisam et al., 1995; Axtell, Tchou, & Akhtar, 1991; Hook & Marchlinski, 1991; Leitch et al., 1991; Bocker et al., 1996)
4. Nonsustained VT in patients with coronary disease, prior myocardial infarction, LV dysfunction, and inducible VF or sustained VT at electrophysiological study that is not suppressible by a Class I antiarrhythmic drug. (Level of evidence: A) (Moss et al., 1996; Saksena et al., 1997; Buxton et al., 1999)
5. Spontaneous sustained VT in patients without structural heart disease not amenable to other treatments. (Level of evidence: C)

Class IIa

1. Patients with left ventricular ejection fraction of less than or equal to 30% at least 1 month post myocardial infarction and 3 months post coronary artery revascularization surgery. (Level of evidence: B) (Moss et al., 2002)

Class IIb

1. Cardiac arrest presumed to be due to VF when electrophysiological testing is precluded by other medical conditions. (Level of evidence: C) (Crandall et al., 1993; Wever et al., 1995; Bardy, Yee, & Jung, 1996; Groh et al., 1996)
2. Severe symptoms (e.g., syncope) attributable to ventricular tachyarrhythmias in patients awaiting cardiac transplantation. (Level of evidence: C) (Grimm et al., 1995; Sweeney et al., 1995)
3. Familial or inherited conditions with a high risk for life-threatening ventricular tachyarrhythmias such as long QT syndrome or hypertrophic cardiomyopathy. (Level of evidence: B) (Donoso, Adler, & Friedberg, 1964; DePasquale & Bruno, 1973; Garson et al., 1993; McKenna & Franklin, 1988; Fananapazir & Epstein, 1991; Wichter et al., 1993; Evans et al., 1993; Maron & Fananapazir, 1992; Kaminer et al., 1990)
4. Nonsustained VT with coronary artery disease, prior MI, LV dysfunction, and inducible sustained VT or VF at electrophysiological study. (Level of evidence: B) (Mehta et al., 1992; Tchou et al., 1988; Zipes & Roberts, 1995; Moss et al., 1996; Saksena et al., 1997; Mehta et al., 1993; Wilber et al., 1990)
5. Recurrent syncope of undetermined origin in the presence of ventricular dysfunction and inducible ventricular arrhythmias at electrophysiologic study when other causes of syncope have been excluded. (Level of evidence: C)
6. Syncope of unexplained origin or family history of unexplained sudden cardiac death in association with typical or atypical right bundle-branch block and ST-segment elevations (Brugada syndrome). (Level of evidence: C) (Brugada, Brugada, & Brugada, 2000; Priori et al., 2002)
7. Syncope in patients with advanced structural heart disease in whom thorough invasive and noninvasive investigations have failed to define a cause. (Level of evidence: C)

Class III

1. Syncope of undetermined cause in a patient without inducible ventricular tachyarrhythmias and without structural heart disease. (Level of evidence: C)
2. Incessant VT or VF. (Level of evidence: C)
3. VF or VT resulting from arrhythmias amenable to surgical or catheter ablation; for example, atrial arrhythmias associated with the Wolff-Parkinson-White syndrome, right ventricular outflow tract VT, idiopathic left ventricular tachycardia, or fascicular VT. (Level of evidence: C) (Morady et al., 1993; Stevenson et al., 1993; Gonska et al., 1994; Hindricks, 1993; Klein et al., 1992)
4. Ventricular tachyarrhythmias due to a transient or reversible disorder (e.g., AMI, electrolyte imbalance, drugs, trauma) when correction of the disorder is considered feasible and likely to substantially reduce the risk of recurrent arrhythmia. (Level of evidence: B) (Michaud et al., 2001; Michaud & Strickberger, 2001; Anderson et al., 1999)

5. Significant psychiatric illnesses that may be aggravated by device implantation or may preclude systematic follow-up. (Level of evidence: C) (Vlay et al., 1989; Luderitz et al., 1993)
6. Terminal illnesses with projected life expectancy less than 6 months. (Level of evidence: C)
7. Patients with coronary artery disease with LV dysfunction and prolonged QRS duration in the absence of spontaneous or inducible sustained or nonsustained VT who are undergoing coronary bypass surgery. (Level of evidence: B) (Bigger, 1997)
8. New York Heart Association (NYHA) Class IV drug-refractory congestive heart failure in patients who are not candidates for cardiac transplantation. (Level of evidence: C)

Definitions:

Level of Recommendation: The final recommendations for indications for device therapy are expressed in the standard ACC/AHA format as follows:

Class I: Conditions for which there is evidence and/or general agreement that a given procedure or treatment is beneficial, useful, and effective.

Class II: Conditions for which there is conflicting evidence and/or a divergence of opinion about the usefulness/efficacy of a procedure or treatment.

> Class IIa: Weight of evidence/opinion is in favor of usefulness/efficacy.
>
> Class IIb: Usefulness/efficacy is less well established by evidence/opinion.

Class III: Conditions for which there is evidence and/or general agreement that a procedure/treatment is not useful/effective and in some cases may be harmful.

Strength of Evidence:

A. Data derived from multiple randomized clinical trials involving a large number of individuals.
B. Data derived from a limited number of trials involving a comparatively small number of patients or from well-designed data analyses of nonrandomized studies or observational data registries.
C. Consensus opinion of experts

## CLINICAL ALGORITHM(S)

Algorithms are provided in the original guideline document for:

- Selection of Pacemaker Systems for Patients with Atrioventricular (AV) Block
- Selection of Pacemaker Systems for Patients with Sinus Node Dysfunction

## EVIDENCE SUPPORTING THE RECOMMENDATIONS

### REFERENCES SUPPORTING THE RECOMMENDATIONS

References open in a new window

### TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations").

In the narrative portions of these guidelines, evidence is generally presented in chronological order of development. Studies are identified as observational, randomized, prospective, or retrospective. The committee emphasizes that for certain conditions for which no other therapy is available, the indications for device therapy are based on expert consensus and years of clinical experience and are thus well supported, even though the evidence was ranked as level C. When indications at level C are supported by historical clinical data, appropriate references (case reports, clinical reviews, etc.) are cited if available. When level C indications are based strictly on committee consensus, no references are cited. In areas where sparse data were available (e.g., pacing in children and adolescents), a survey of current practices of major centers in North America was conducted to determine if there was a consensus regarding specific pacing indications.

## BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

### POTENTIAL BENEFITS

- Appropriate use of devices (pacemakers and implantable cardioverter-defibrillators)
- Decreased morbidity and mortality in patients requiring implantation of cardiac pacemakers or cardioverter-defibrillators

#### Subgroups Most Likely to Benefit:

#### Pacing in Hypertrophic Obstructive Cardiomyopathy

Patients who may benefit the most are those with significant gradients (more than 30 mm Hg at rest or more than 50 mm Hg provoked).

#### Implantable Cardioverter-Defibrillator (ICD) Therapy

Patients with reduced left ventricular (LV) systolic function appear to benefit the most from ICD therapy.

### POTENTIAL HARMS

#### Implantable Cardioverter-Defibrillator (ICD) Therapy

#### Contraindications/Limitations

- ICD therapy is not recommended for patients in whom a reversible triggering factor for ventricular tachycardia/ventricular fibrillation (VT/VF) can be definitively identified, such as ventricular tachyarrhythmias in evolving acute myocardial infarction (AMI) or electrolyte abnormalities.
- Coronary disease patients without inducible or spontaneous ventricular tachycardia undergoing routine coronary bypass surgery are not routine candidates for ICD therapy.
- Patients with Wolff-Parkinson-White syndrome presenting with VF secondary to atrial fibrillation should undergo catheter or surgical ablation if their accessory pathways are amenable to such treatment.
- Patients with terminal illnesses, New York Heart Association (NYHA) class IV drug-refractory congestive heart failure who are not candidates for cardiac transplantation, or with a life expectancy not exceeding 6 months are likely to obtain limited benefit, if any, from ICD therapy. Thus, ICD therapy is discouraged in such individuals.
- A history of psychiatric disorders, including uncontrolled depression and substance abuse that interfere with the meticulous care and follow-up needed by these patients, is a relative contraindication to device therapy.
- Patients who have frequent tachyarrhythmias that may trigger shock therapy, such as sustained ventricular tachycardia not responsive to antitachycardia pacing or pharmacological therapy, are not suitable candidates for a device because these events would cause frequent device activation and multiple shocks. Alternative therapies, such as combining drugs or ablation with ICD insertion, should be considered.

## QUALIFYING STATEMENTS

### QUALIFYING STATEMENTS

- These practice guidelines are intended to assist physicians in clinical decision-making by describing a range of generally acceptable approaches for the diagnosis, management, or prevention of specific diseases or conditions. The guidelines attempt to define practices that meet the needs of most patients in most circumstances. The ultimate judgment regarding care of a particular patient must be made by the physician and patient in light of all of the circumstances presented by that patient.
- The committee considered including a section on extraction of failed/unused leads, a topic of current interest, but elected not to do so in the absence of convincing evidence to support specific criteria for timing and methods of lead extraction.
- The text accompanying the listed recommendations should be read carefully because it includes the rationale and supporting evidence for many of the recommendations, and in several instances it includes a discussion of alternative acceptable therapies. Many of the indications are modified by the term "potentially reversible." This term is used to indicate abnormal pathophysiology (e.g., complete heart block) that may be the result of reversible factors. Examples include complete heart block due to drug toxicity (digitalis), electrolyte abnormalities, diseases with inflammatory periatrioventricular node reaction (Lyme disease), transient injury to the conduction system at the time of open heart surgery, and others. When faced with a potentially reversible situation, the treating physician must decide how long a waiting period is justified before beginning device therapy. The

committee recognizes that this statement does not address issues of length of hospital stay vis-a-vis managed-care regulations. It is emphasized that these guidelines are not intended to address this issue, which falls strictly within the purview of the treating physician.

## IMPLEMENTATION OF THE GUIDELINE

### DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

## INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

### IOM CARE NEED

Living with Illness

### IOM DOMAIN

Effectiveness

## IDENTIFYING INFORMATION AND AVAILABILITY

### BIBLIOGRAPHIC SOURCE(S)

ACC/AHA/NASPE 2002 guideline update for implantation of cardiac pacemakers and antiarrhythmia devices. Bethesda (MD): American College of Cardiology Foundation; 2002. 48 p. [447 references]

### ADAPTATION

Not applicable: The guideline was not adapted from another source.

### DATE RELEASED

1998 Apr (revised 2002 Sep)

### GUIDELINE DEVELOPER(S)

American College of Cardiology Foundation - Medical Specialty Society
American Heart Association - Professional Association
Heart Rhythm Society - Professional Association

### SOURCE(S) OF FUNDING

Funded by the American College of Cardiology Foundation (ACCF), the American Heart Association (AHA), and the North American Society of Pacing and Electrophysiology (NASPE). No outside funding is accepted.

## GUIDELINE COMMITTEE

ACC/AHA/NASPE Committee to Update Guidelines on Cardiac Pacemaker Implantation and Antiarrhythmic Devices

## COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

The committee to revise the ACC/AHA Guidelines for Implantation of Cardiac Pacemakers and Antiarrhythmia Devices was composed of both university-affiliated and practicing physicians. It included experts in the area of device therapy and follow-up, senior clinicians skilled in cardiovascular care, a general internist, and a cardiothoracic surgeon. The committee included representatives of the American College of Physicians, NASPE, and the Society of Thoracic Surgeons.

Committee Members: Gabriel Gregoratos, MD, FACC, FAHA (Chair); Jonathan Abrams, MD, FACC, FAHA; Andrew E. Epstein, MD, FACC, FAHA; Roger A. Freedman, MD, FACC; David L. Hayes, MD, FACC, FAHA; Mark A. Hlatky, MD, FACC, FAHA; Richard E. Kerber, MD, FACC, FAHA; Gerald V. Naccarelli, MD, FACC, FAHA; Mark H. Schoenfeld, MD, FACC, FAHA; Michael J. Silka, MD, FACC; Stephen L. Winters, MD, FACC

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## FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

The American College of Cardiology/American Heart Association (ACC/AHA) Task Force on Practice Guidelines makes every effort to avoid any actual or potential conflicts of interest that might arise as a result of an outside relationship or personal interest of a member of the writing panel. Specifically, all members of the writing panel are asked to provide disclosure statements of all such relationships that might be perceived as real or potential conflicts of interest. These statements are reviewed by the parent task force, reported orally to all members of the writing panel at the first meeting, and updated yearly and as changes occur.

## GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previously released version: Gregoratos G, Cheitlin MD, Conill A, Epstein AE, Fellows C, Ferguson TB Jr, Freedman RA, Hlatky MA, Naccarelli GV, Saksena S, Schlant RC, Silka MJ, Ritchie JL, Gibbons RJ, Cheitlin MD, Eagle KA, Gardner TJ, Lewis RP, O'Rourke RA, Ryan TJ, Garson A Jr. ACC/AHA guidelines for implantation of cardiac pacemakers and antiarrhythmia devices: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Committee on Pacemaker Implantation). J Am Coll Cardiol 1998 Apr;31(5):1175-209.

These guidelines will be reviewed 1 year after publication and yearly thereafter and considered current unless the Task Force on Practice Guidelines revises or withdraws them from circulation.

## GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the American College of Cardiology Web site.

Electronic copies are also available in Portable Document Format from the American Heart Association (AHA) Web site and the North American Society of Pacing and Electrophysiology Web site.

Print copies: Single copies available from the American College of Cardiology, Resource Center, 9111 Old Georgetown Rd., Bethesda, MD 20814-1699; (800) 253-4636 (US only). Bulk reprints available from AHA, Public Information, 7272 Greenville Ave., Dallas TX 75231-4596; Reprint No. 71-0237.

## AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- ACC/AHA/NASPE 2002 Guideline Update for Implantation of Cardiac Pacemakers and Antiarrhythmia Devices: Summary Article: A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (ACC/AHA/NASPE Committee to Update the 1998 Pacemaker Guidelines). Circulation 2002 Oct 15;106(16):2145-61; J Am Coll Cardiol 2002 Nov 6;40(9):1703-19; J Cardiovasc Electrophysiol 2002 Nov;13(11):1183-99.

Electronic copies: Available in Portable Document Format (PDF) from the American College of Cardiology (ACC), the American Heart Association (AHA), and the North American Society of Pacing and Electrophysiology (NASPE) Web sites.

Print copies: Single copies available from the American College of Cardiology, Resource Center, 9111 Old Georgetown Rd., Bethesda, MD 20814-1699; (800) 253-4636 (US only). Bulk reprints available from AHA, Public Information, 7272 Greenville Ave., Dallas TX 75231-4596; Reprint No. 71-0236.

The following is also available:

- ACC/AHA pocket guidelines for implantation of cardiac pacemakers and antiarrhythmia devices.

Electronic copies available from the ACC Web site: Pocket Guideline; or Pocket Guideline Palm Download.

Print copies available from ACC, Resource Center, 9111 Old Georgetown Rd, Bethesda, MD 20814-1699; (800) 253-4636 (US only). Bulk reprints available from AHA, Public Information, 7272 Greenville Ave, Dallas TX 75231-4596.

## PATIENT RESOURCES

None available

## NGC STATUS

This summary was completed by ECRI on November 3, 1998. The information was verified by the guideline developer as of May 14, 1999. This summary was updated by ECRI on January 9, 2003. The updated information was verified by the guideline developer on June 12, 2003.

## COPYRIGHT STATEMENT



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